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Attorney's Docket No. **498-239**

PATENT

JC841 U.S. PTO 09/660078 09/11/00

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Box Patent Application
Assistant Commissioner for Patents
Washington, D.C. 20231

NEW APPLICATION TRANSMITTAL

Transmitted herewith for filing is the patent application of

Inventor(s): **SMITH, John K.**, a U.S. citizen whose address is:
44 Sawyer Avenue; Medford, MA 02155

For (title): **ENDOVASCULAR PROSTHETIC DEVICES HAVING HOOK AND LOOP STRUCTURES**

"Express Mail" Mailing Label No. EL023541993US

CERTIFICATION UNDER 37 CFR 1.10

I hereby certify that this New Application Transmittal and the documents referred to as enclosed herein are being deposited with the United States Postal Service on this date, September 11, 2000, in an envelope as "Express Mail to Addressee" Mailing Label Number **EL023541993US** addressed to the Commissioner of Patents and Trademarks, Washington, D.C. 20231.

Kathleen J. Goodhand
Name of person mailing paper

Kathleen J. Goodhand
Signature of person mailing paper

1. **Type of Application**

This new application is a(n):

[X] Original (nonprovisional) application under

[X] 37 CFR 1.53(b)

[ ] Divisional of Serial No. _____, filed on _____, under

[ ] 37 CFR 1.53(b) [ ] 37 CFR 1.53(d) [CPA]

[ ] Continuation of Serial No. _____, filed on_____, under

[ ] 37 CFR 1.53(b) [ ] 37 CFR 1.53(d) [CPA]

[ ] Continuation-in-part of Serial No. _____, filed on _____, under

[ ] 37 CFR 1.53(b)

[ ] Design application.

[ ] Plant application.

2. **Benefit of Prior U.S. Application(s) (35 U.S.C. 119(e), 120, or 121)**

[ ] This new application claims the benefit of prior U.S. application(s).

[ ] Please amend the specification by inserting, before the first line, the following:

[ ] "This application claims the benefit of U.S. Provisional Application No. _____, filed on _____."

[ ] "This application is a
[ ] continuation
[ ] continuation-in-part
[ ] divisional
of copending application
[ ] Serial No. 08/____, filed on_____."
[ ] International Application No. _____, filed on _____, and which designated the U.S."

[ ] A Preliminary Amendment is enclosed amending this application to state the relation of this application to prior applications.

[ ] The relation of this application to prior applications is stated in the application.

3. **35 U.S.C. 119 Priority Claim for Prior Application**

This application, and prior U.S. application(s), including any prior International Application designating the U.S., identified above in item 2, claim(s) priority from one or more foreign applications as follows:

(Country)	(Application No.)	(Filing Date)
(Country)	(Application No.)	(Filing Date)

Certified copy(ies) of the application(s) from which priority is claimed:

[ ] has(have) been filed on _____, in prior application **0 /** _____, which was filed on _____.
[ ] is (are) enclosed.
[ ] will follow.

4. **Papers Enclosed Which are Required to Obtain Application Filing Date under 37 CFR 1.53(b) (Regular) or 37 CFR 1.153 (Design)**

21 Pages of specification
6 Pages of claims
1 Pages of Abstract
4 Sheets of drawings
[ ] formal
[X] informal

[ ] The enclosed drawing(s) include photograph(s), and there is also attached a "Petition to Accept Photograph(s) as Drawings." 37 CFR 1.84(b).

5. **Additional Papers Enclosed**

[ ] Preliminary Amendment

[X] Information Disclosure Statement (37 CFR 1.98)

[X] Form PTO-1449

[ ] Citations

[ ] Declaration of Biological Deposit

[ ] Submission of "Sequence Listing," computer readable copy and/or amendment pertaining thereto for biotechnology invention containing nucleotide and/or amino acid sequence

[ ] Authorization of Attorney(s) to Accept and Follow Instructions from Representative

[ ] Special Comments

[ ] Power of Attorney

[ ] Other

6. Declaration or Oath

[X] A Declaration or Oath is enclosed, executed by (check all applicable boxes):

[X] inventor(s).

[ ] legal representative(s) of inventors(s) (37 CFR 1.42 or 1.43).

[ ] joint inventor or person showing a proprietary interest on behalf of inventor who refused to sign or cannot be reached.

[ ] This transmittal serves as the petition required under 37 CFR 1.47, and the statement required under 37 CFR 1.47 is also enclosed. See item 13 below for fee.

[ ] A Declaration or Oath was filed on _____ in prior application **0 /** _____, filed on _____, from which benefit is being claimed for this application under 35 U.S.C. 120 or 121. The subject matter disclosed in the present application is the same as that disclosed in the prior application, and the inventors are the same or less than those named in the prior application. Accordingly, no new Oath or Declaration is required.

[ ] A copy of the Oath or Declaration in the prior application is enclosed.

[ ] A Declaration or Oath is not enclosed.

[ ] Application is made by a person authorized under 37 CFR 1.41(c) on behalf of *all* of the above named inventor(s).

[X] A Power of Attorney is included in the Declaration or Oath.

7. **Language**

This new application is written in:

[X] English.

[ ] A non-English language: _____.
[ ] A verified translation is enclosed (37 CFR 1.52(d)).

8. **Assignment**

[X] An assignment of the invention to **Scimed Life Systems, Inc.**
One Scimed Place, Maple Grove, MN 55311-1566

[X] is enclosed. A separate:

[ ] "Cover Sheet for Assignment (Document) Accompanying New Patent Application" is enclosed.

[X] Form PTO-1595 is enclosed.

[ ] was made in prior application No. 0 /_____, filed on _____.

[ ] A copy of the assignment (and any recordation cover sheet) is enclosed.

[ ] will follow.

9. **Maintenance of Copendency of Prior Application**

[ ] A Petition for Extension of Time and the appropriate fee has been filed and extends the term in the pending prior application until _____.

[ ] A copy of the petition filed in the prior application is attached.

[ ] A conditional petition for extension of time is being filed in the pending prior application.

[ ] A copy of the conditional petition in the prior application is attached.

10. **Abandonment of Prior Application**

[ ] Please abandon the prior application at a time while the prior application is pending, or when the petition for extension of time or to revive in that application is granted, and when this application is granted a filing date, so as to make this application copending with said prior application.

11. Petition for Suspension of Prosecution for the Time Necessary to File an Amendment

[ ] There is provided herewith a Petition to Suspend Prosecution for the Time Necessary to File an Amendment.

12. Fee Calculation (37 CFR 1.16)

A. [X] Regular application (37 CFR 1.16(a)) Basic Fee $ **690.00**

FEES FOR CLAIMS AS FILED

	Number filed		Number extra		Rate		
Total Claims (37 CFR 1.16(c))	**27**	- 20 =	**7**	X	$ 18.00	=	$ **126.00**
Independent Claims (37 CFR 1.16(b))	**6**	- 3 =	**3**	X	$ 78.00	=	$ **234.00**
Multiple Dependent Claims (37 CFR 1.16(d))				+	$260.00=		$

Fee Calculation for Extra Claims $ **360.00**

[ ] Amendment canceling extra claims enclosed.
[ ] Amendment deleting multiple-dependencies enclosed.

B. [ ] Design application (37 CFR 1.16(f)) Filing Fee $330.00

C. [ ] Plant application (37 CFR 1.16(g)) Filing Fee $540.00

Total Filing Fee Calculation **$1,050.00**

13. Request for International-Type Search (37 CFR 1.104(d))

[ ] Please prepare an international-type search report for this application at the time national examination on the merits takes place. See item 15 for fee.

14. Small Entity Statement(s)

[ ] A Verified Statement that this is a filing by a small entity under 37 CFR 1.9 and 1.27;
[ ] is enclosed.
[ ] will follow.

[ ] Status as a small entity was claimed in prior application **0 /** _____, filed on _____, from which benefit is being claimed for this application under:
[ ] 35 U.S.C. 119(e),
[ ] 35 U.S.C. 120,
[ ] 35 U.S.C. 121,
[ ] 35 U.S.C. 365(c),

and which status as a small entity is still proper and desired.

[ ] A copy of the verified statement in the prior application is enclosed.

Filing Fee Calculation (50% of **A**, **B**, or **C** above) $

15. Fee Payment Being Made at This Time

[ ] Not enclosed. No filing fee is to be paid at this time.

[X] Enclosed:

[X]	Basic filing fee (Item 12 or 14 above)	$ **1,050.00**
[X]	Fee for recording Assignment ($40.00 (37 CFR 1.21(h)))	$ **40.00**
[ ]	Petition fee for filing by other than all of the inventors or person on behalf of the inventor where inventor refused to sign or cannot be reached. ($130.00 (37 CFR 1.47 and 1.17(h)))	$
[ ]	Fee for processing an application having a specification in a non-English language. ($130.00 (37 CFR 1.52(d) and 1.17(k)))	$
[ ]	Processing and retention fee ($130.00 (37 CFR 1.53(d) and 1.21(l)))	$
[ ]	Fee for international-type search report ($40.00 (37 CFR 1.21(e)))	$
	Total fees enclosed	$ **1,090.00**

JC841 U.S. PTO
09/660078
09/11/00

16. Method of Payment of Fees

[X] Check in the amount of $ **$1,090.00**

[ ] Charge Deposit Account No. 08-2461 in the amount of $____________. A duplicate of this transmittal is enclosed.

17. Authorization to Charge Additional Fees

[X] The Commissioner is hereby authorized to charge the following additional fees by this paper and during the entire pendency of this application to Deposit Acc'nt No. 08-2461:

[X] 37 CFR 1.16(a), (f), or (g) (filing fees)

[X] 37 CFR 1.16(b), (c), and (d) (presentation of extra claims)

[ ] 37 CFR 1.16(e) (surcharge for filing the basic fee and/or declaration at a date later than the filing date of the application)

[ ] 37 CFR 1.17 (application processing fees)

A duplicate of this transmittal is enclosed.

18. Instructions as to Overpayment

[X] Credit Deposit Account 08-2461.

[ ] Refund.

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09660078.091100

Docket: 498-239 Patent

ENDOVASCULAR PROSTHETIC DEVICES HAVING HOOK AND LOOP STRUCTURES

Inventor: John K. Smith

ENDOVASCULAR PROSTHETIC DEVICES HAVING HOOK AND LOOP STRUCTURES

FIELD OF THE INVENTION

The present invention is directed to multiple-component endovascular prostheses having textile structures of mating hooks and loops, which maintain the components of the prostheses in substantially fluid tight engagement with one another. More particularly, the present invention is directed to bifurcated endovascular prostheses comprised of two or more stent-graft components having textile structures of hooks and loops which may be assembled *in situ* for use in bifurcated blood vessels, such as the infrarenal portion of the mammalian aortic artery where it bifurcates to the common iliac arteries.

DOCKET ALARM

BACKGROUND OF THE INVENTION

An abdominal aortic aneurysm ("AAA") is an abnormal dilation of the arterial wall of the aorta in the region of the aorta that passes through the abdominal cavity. The condition most commonly results from atherosclerotic disease. Abdominal aortic aneurysms are typically dissecting aneurysms, which are aneurysms that are formed when there is a tear or fissure in the arterial lining or wall through which blood is forced and

eventually clots, forming a thrombosis which swells and weakens the vessel. Abdominal aortic aneurysms typically do not cause pain and are easily detected by physical examination. The aneurysm may rupture if it is not detected and treated, causing massive hemorrhaging which is likely to be fatal to the patient.

Treatment of AAAs typically comprises some form of arterial reconstructive surgery, commonly referred to as a "triple-A" procedure. One such method is bypass surgery, in which an incision is made into the abdominal cavity, the aorta is closed off above and below the site of the aneurysm, the aneurysm is resected, and a synthetic graft or tube sized to approximate the diameter of the normal aorta is sutured to the vessel to replace the aneurysm and to allow blood flow through the aorta to be reestablished. The graft commonly is fabricated of a thin-walled biocompatible material. Nylons and synthetic fibers, such as DACRON® and TEFLON®, are typically used in the construction of such grafts. When performed prior to rupture of an aneurysm, the mortality rate is less than 5%.

Many patients experiencing such AAAs, however, are over 65 years of age and often have other chronic illnesses which increase the risk of perioperative or post-operative complications. Thus, such patients are not ideal candidates for triple-A procedures. Further, this procedure is generally not performed successfully once an aneurysm has ruptured due to the extensiveness of the surgery and the time required to prepare a patient for surgery. The mortality rate for patient experiencing such ruptured aneurysms is over 65%.

As a result of the aforementioned disadvantages to conventional surgical methods, minimally invasive techniques have been developed for the repair of AAAs. Such methods involve placement of a stent-graft at the site of the aneurysm by a catheter, known as an introducer, which serves as a deployment device. The stent-graft and its deployment system are typically introduced into the blood stream percutaneously and negotiated by means of a guidewire to the site of the aneurysm where the stent is caused to be radially expanded. Such procedures are desirable as they can be performed using local anesthesia and do not expose the patient to many of the same risks associated with triple-A procedures.

In such minimally invasive repair procedures, the bifurcated structure of the abdominal aortic arch necessitates the use of a uniquely-structured bifurcated stent-graft. Typically, aneurysms, occlusions or stenoses will occur at the location where the aortic arch bifurcates into the iliac arteries and may also occur at the iliac arteries. The *in situ* positioning of stent-grafts in this area is more difficult than the positioning of such devices in the lumen of non-bifurcated vessels. As both limbs of a bifurcated stent-graft are inserted and advanced through a single branch of the femoral arterial system, one of the limbs of the stent-graft must ultimately be pulled or drawn into the contralateral branch so that the stent-graft is suitably positioned across both the aortic aneurysm and the associated common iliac aneurysms to supply circulation to each of the lower limbs.

Bifurcated stent-grafts are frequently too bulky to advance through a single iliac artery, particularly in view of the fact that the limb for the contralateral branch of the stent-graft must be inserted together with the limb of the ipsilateral branch. Additionally, care must be taken to not twist or kink the stent-graft as it is placed in the contralateral artery. The caudal portion of the graft must not stretch across the mouth of the internal iliac artery which would result in inadvertent occlusion of that artery. The procedure of drawing one limb of the stent-graft from one femoral artery to the contralateral femoral artery requires placement of a cross-femoral catheter using a closable wire basket prior to insertion of the stent-graft.

This procedure requires significant and skillful wire catheter manipulation, frequently within the aneurysmal cavity. As such, care must be taken to avoid disturbing or dislodging thrombic or embolic material from within the aneurysmal sac. Additional factors such as the severe tortuosity of the iliac arteries and the marked angulation of the aortoiliac junction resulting form the tendency of the abdominal aortic artery to extend caudally during aneurysm formation combine to make deployment of endoluminal bifurcated grafts time consuming and at increased risk of procedural complications and failure.

To overcome the aforementioned risks associated with the use of one-piece stent-grafts in the repair of aneurysms occurring in bifurcated vessels, two-piece stent-grafts have been developed which may be assembled *in situ*. Examples of such two-piece stent-grafts are disclosed in U.S. Patent Nos. 6,051,020, 5,938,696, and 5,916,263, all to

Goicoechea et al., wherein a first stent-graft is positioned within one branch of the femoral arterial system and a second stent-graft is subsequently positioned with a contralateral branch thereof and attached to the first component. Attachment of the components typically occurs by overlapping sections of the components which are held together by friction forces.

Additionally, prosthetic devices used in the repair of AAAs have been found to be extremely vulnerable to wearing, particularly as a result of the tortuous nature of vessel lumens. Such wearing necessitates the repair of these devices, requiring additional surgical procedures which may include replacement of the device. Consequently, there is a continuing need for the development of stent grafts and techniques useful for the repair of AAAs and for the repair of AAA devices.

SUMMARY OF THE INVENTION

Accordingly, the present invention is directed to an improved endovascular prosthesis and methods of repairing aneurysms, occlusions, and stenoses using such a prosthesis, wherein the prosthesis includes stent-graft components having hook and loop structures which permit the *in situ* assembly of the prosthesis while maintaining the components thereof in substantially fluid tight engagement with one another.

Additionally, the present invention is directed to an endovascular prosthesis and method of repairing the same, wherein the prosthesis includes a patch for the repair of a

worn section of an endovascular member. The member and patch have hook and loop structures cooperative with one another such that the patch may be introduced endovascularly and applied to the stent-graft *in situ*, thereby forming a fluid-tight seal over the worn area. Endovascular introduction of the patch permits repair of the damaged endovascular member in an effective and minimally-invasive manner.

In one aspect, the present invention is directed to an endovascular prosthesis which includes: (1) an endovascular member having a structure comprising one of a hook structure and a loop structure; and (2) a patch for placement against the endovascular member which has a structure comprising the other of the hook structure and the loop structure. The hook and loop structures are matingly engageable so as to maintain the patch in substantially fluid tight engagement with the endovascular member. Further, the endovascular member may be a graft, stent or stent-graft and the hook and loop structures may be comprised of textile materials. The loops may also be formed from polypropylene, polyethylene teraphthalate, polyurethane, a copolyester elastomer, or nylon.

In a method aspect, the present invention is directed to a method of repairing a damaged area of an endovascular prosthesis having a hook or loop structure and which is positioned within a body lumen. The method includes the step of attaching *in situ* a patch to an endovascular member, wherein the patch has a hook or loop structure cooperative with a hook or loop structure of the endovascular member which maintains the patch in substantially fluid tight communication with the endovascular member. The patch may

be delivered to the endovascular member through a body lumen containing the endovascular member, such as through the use of a balloon catheter. Further, the patch may be attached to the endovascular member by expanding a balloon affixed to a catheter which causes the hook or loop structure of the patch to engage the other of the hook or loop structure of the endovascular member.

In another aspect, the present invention is directed to a multi-component endovascular prosthesis which includes: (1) a first prosthetic component which has a structure comprising one of a hook structure and a loop structure; and (2) a second prosthetic component which has a structure comprising the other of the hook structure and the loop structure. The hook structure and the loop structures are matingly engageable so as to maintain the first prosthetic component in substantially fluid tight engagement with the second prosthetic component.

In another aspect, the present invention is directed to a bifurcated endovascular prosthesis which includes: (1) a main prosthetic component which has a structure comprising one of a hook structure and a loop structure; and (2) a branch prosthetic component which has a structure comprising the other of the hook structure and the loop structure. The hook and loop structures are matingly engageable so as to maintain the main prosthetic component in substantially fluid tight engagement with the branch prosthetic component.

In a further method aspect, the present invention is directed to a method for the assembly of an endovascular prosthesis which is implantable within a body lumen, which includes the steps of: (1) providing a first prosthetic component having one of a hook or loop structure; (2) providing a second prosthetic component having the other of the hook or loop structure; and (3) engaging *in situ* the hook structure or the loop structure of the first prosthetic component with the other of the hook structure or the loop structure of the second prosthetic component so as to maintain the first prosthetic component in substantially fluid tight engagement with the second prosthetic component. The endovascular prosthesis is useful for the treatment of aneurysms, particularly abdominal aortic aneurysms.

BRIEF DESCRIPTION OF THE DRAWING

Figure 1 is a diagrammatic view of the abdominal aortic arch of the human vascular system depicting the descending aorta and the right and left common iliac arteries.

Figure 2 is a diagrammatic view of a portion of a human vascular system depicting an abdominal aortic aneurysm and associated aneurysms of the left and right common iliac arteries.

Figure 3 shows an abdominal aortic stent-graft and patch therefore.

Figure 4 shows the *in situ* deployment of the patch shown in Figure 3.

Figure 5 shows a hook and loop structure of the present invention wherein the hooks are matingly engaged with the loops.

Figure 6 shows a detailed view of a loop structure used in the present invention.

Figure 7 shows a detailed view of a hook structure used in the present invention.

Figure 8 shows an endovascular prosthesis of the present invention which includes two stent-graft components having hook and loop structures.

Figure 9 shows the endovascular prosthesis of Figure 8 with the stent-graft components matingly engaged through the attachment of the hooks and loops.

Figure 10 shows an endovascular prosthesis of the present invention which includes two stent-graft components having hook and loop structures in an arrangement opposite that shown in Figure 8.

DETAILED DESCRIPTION OF THE INVENTION

The present invention is directed to a multi-component endovascular prosthesis which includes multiple stent components covered with grafts, the endovascular

prosthesis being hereinafter referred to as a prosthesis. The components have hook and loop structures which are matingly engageable, i.e. complementary, so as to maintain them in substantially fluid tight engagement with one another. The hook and loop textile structures may be formed from any biocompatible material such as, for example, material sold under the tradename Velcro® and described in U.S. Patent Nos. 3,748,701 to De Mestral, 3,943,981 to De Brabander, 3,594,873 to Hockmeyer et al., and 3,577,607 to Ikoma et al., all incorporated by reference herein.

The present invention is well-suited for the repair of aneurysms, occlusions, stenoses, and other blood vessel conditions typically resulting from atherosclerotic disease and repaired using a stent, graft, or stent-graft prosthesis. Additionally, dissections of blood vessels, such as those due to blunt trauma to, for example, the chest, are also well-suited for repair by devices of the present invention. A prosthesis of the present invention is capable of being introduced into the body as multiple components and then assembled *in situ*. Such assembly allows for precise positioning of the prosthesis and avoids complications, such as inadvertent occlusions and the dislodging of thrombic or embolic material, associated with the use of one-piece stent-grafts, particularly in bifurcated vessels.

Assembly of the components is accomplished by engaging cooperative hook and loop structures of the components. The components are overlapped sufficiently to permit the hook and loop structures to engage one another when the components are placed in a face-to-face arrangement, forming a substantially fluid-tight seal therebetween. Any

number of components can be assembled in this manner, thus permitting the surgeon a great deal of flexibility in the manner in which the prosthesis will be positioned within the lumen of blood vessels. By assembling the components *in situ*, smaller members are drawn through the lumen than as with one-piece prosthetic devices. Additionally, twisting of the prosthesis in the lumen in order to properly position it is avoided, thereby decreasing the risk of incidental damage to the vessel and thrombi release into the vessel stream.

The present invention is also well suited to the *in situ* repair of a damaged endovascular member (e.g., a stent graft) which, for example, has become worn due to tortuous blood flow. Such repair may occur by patching or replacing a worn area of the member. The patch used in the repair has a hook or loop structure which is complementary to a hook or loop structure of the member in need of repair. As such, the repair material cooperatively engages the material of the member resulting in a substantially fluid-tight seal therebetween, thereby permitting the effective and complete repair of the damaged area using minimally invasive techniques.

A stent useful in the present invention is an intraluminal stent having any number of configurations and may include attachment hooks to assist in attaching the stent to the aortic wall after the stent has been expanded. Other types of stents are useful in the present invention, including expandable stents without hooks or self-expanding stents with or without attachment hooks. Stents useful in the present invention can be made from metals or polymers and have numerous configurations.

The present invention is suited for use with conventional stents, grafts, and stent-graft devices, and therefore is suitable for use in all known vascular applications employing such devices. As the hook and loop structures of the mating parts provides a strong and substantially fluid-tight seal therebetween, the present invention is well suited to use in any vessel where a prostheses are susceptible to wear (e.g., where extreme tortuosity is encountered) and where it is advantageous to assemble such prostheses *in situ*.

Referring to Figure 1, the abdominal aortic arch 100 of the human vascular system is shown. The arch includes the abdominal aorta 102 and the right and left common iliac arteries 104 and 104′, respectively. In a diseased state, aneurysmal sacs form around these structures, resulting in abdominal aortic aneurysm 106 and aneurysms 108 and 108′ of the right and left common iliac arteries, respectively, as illustrated in Figure 2.

Referring to Figure 3, a prosthesis 110 of the present invention is shown. Prosthesis 110 includes an endovascular member 112 (e.g., a stent-graft) which is capable of being positioned within the lumen of the abdominal aortic arch 100 for the repair of aneurysms 106, 108, and 108′. As is known in the art, member 112 may include a stent (not shown) and a graft 113 which is supported by the stent. Member 112 includes limbs 114 and 114′ for placement into right common iliac artery 104 and left common iliac artery 104′, respectively, and includes a trunk 116 for placement into the abdominal aorta

102. Member 112, also has a worn area 118 which has been damaged, for example, by the tortuous flow of blood through abdominal aortic arch 100, and is consequently in need of repair.

Any known stent material and structure may be used to form the stent of member 112 of the present invention. For example, the stent may comprise a sinuous wire formed into a tubular configuration and may be made from a shape memory nitinol (nickel titanium) wire, such as that disclosed in U.S. Patent No. 6,051,020 to Goicoechea at al., incorporated by reference herein. Typically, the stent is annealed while on a mandrel at an elevated temperature such that it will "remember" the configuration in which it was wound. As such, the formed stent may be radially compressed in order to introduce it into a body lumen and maneuver it to the aneurysm where it will be caused to radially expand to its original state, thereby providing a prosthetic endoluminal surface to the diseased blood vessel.

Additionally, any known graft material and structure may be used to form the graft 113 of member 112 of the present invention. For example, materials which promote endothelial tissue growth on and through the graft structure are typically used. Such materials include, for example, polyester, polytetrafluoroethylene, expanded polytetrafluoroethylene and polyurethane, but may be any suitable biocompatible material.

While member 112 is desirably a stent-graft, it may be other intraluminal prosthetic devices which are suitable for use in the present invention. Additionally, while member 112 shown in Figures 3-10 is tubular-shaped, this is representative only and other configurations are possible.

Member 112 of the present invention includes a hook or loop structure which is complementary with a hook or loop structure of a patch 120 to be attached thereto. For example, as shown in Figure 3, member 112 has loops 122 on the inner surface thereof. Loops 122, illustrated in greater detail in Figure 6, are formed from a woven or knitted graft material by velouring of the material or of a second material associated therewith. Loops 122 are desirably formed from polypropylene, polyethylene teraphthalate, polyurethane or from a copolyester elastomer, such as that sold under the tradename Hytrel® by E.I. Du Pont de Nemours and Company. Additionally, loops 122 may be formed from any biocompatible material, including nylon or any suitable synthetic polyester fiber, such as Dacron®. Loops 122 may be provided as a tape which is affixed to the stent and/or graft 113.

As shown in Figure 3, member 112 may include a damaged area 118 which is consequently in need of repair. Damaged area 118 results, for example, from the tortuous flow of blood through the lumen of member 112. A patch 120 for the repair of damaged area 118 has hooks 124 on the exterior surface thereof, which may also be in the form of a tape. Hooks 124 are capable of matingly engaging loops 122, as shown in Figure 5, forming a substantially fluid-tight seal between patch 120 and member 112 at damaged

area 118. Hooks 124 and loops 122 may be present on either of the mating elements, it is necessary only that the structures being joined have complementary hook and loop structures.

As shown in Figure 4, a deployment mechanism 126, such as a balloon catheter, is used to introduce patch 120 in a radially compressed state to damaged area 118 using a minimally-invasive endovascular technique, for example, angioplastic techniques. Once delivery device 126 has been maneuvered to align patch 120 with damaged area 118, patch 120 is caused to radially expand causing hooks 124 present thereon to engage loops 122 of member 112.

Hooks 124, shown in greater detail in Figures 7, may be formed from any biocompatible, textile or thermoplastic material. When formed as a tape, hooks 124 can be any suitable fabric-backed microhoop strip. For example, hooks 124 may be formed from any of the aforementioned materials from which loops 122 may be formed from, including, but not limited to, Nylon®, polypropylene, polyethylene, Dacron®, or molded polyethylene terepthalate. Hooks 124 may be formed from a tape which is affixed to a prosthetic member, or may be incorporated into a material of such a member, for example, into a woven material.

Hooks 124 may be made accordingly to any number of known processes. For example, they may be formed by cutting loops 122, as shown in Figure 7, or by applying

heat to an aforementioned thermoplastic material while simultaneously blowing the material in such a manner as to form a hook structure.

Turning to Figures 8, 9 and 10, a prosthesis 130 of the present invention is shown. Prosthesis 130 includes a main stent-graft 132, which comprises the trunk 134 and right limb 136 of prosthesis 130, and includes a branch stent-graft 138, which, when attached to main stent-graft 132, comprises the left limb of prosthesis 130. Hooks 140 and loops 142 of the aforementioned materials and structures are present on main stent-graft 132 and branch stent-graft 138, as shown in Figures 8 and 10, thereby permitting these elements to be joined in fluid-tight engagement, as shown in Figure 9 and as will be described in fuller detail below with reference to the Example.

Examples of multiple-component bifurcated stents and methods of introducing such stents to aneurysms useful in the present invention are described in U.S. Patent Nos. 5,716,365, 5,683,450, 5,718,724, 5,776,180, 5938,696, 5,916,263, and 6,051,020, all to Goicoechea et al., all of which are incorporated herein by reference.

EXAMPLE

IN SITU STENT-GRAFT DEPLOYMENT

For purposes of the present example, the term "proximal" refers to a position nearest the heart and the term "distal" refers to a position furthest from the heart. As

shown in Figure 1, the abdominal aorta 102 extends caudally to the common iliac arteries 104 and 104', which branch to the right and left, respectively. Each common iliac artery branches to an external iliac artery (not shown) which becomes the femoral artery (not shown) below the inguinal ligament (not shown).

Incisions (not shown) are made which expose the common femoral arteries on the right and left sides. A conventional angiographic guidewire (not shown) is inserted into the incised left femoral artery. The guidewire is advanced until its distal end is above the aneurysm within the vasculature. Typically, the guidewire is at least 0.025 inches in diameter and is composed of tempered stainless steel which is covered with a synthetic material, such as TEFLON®. The guidewire typically remains in a fixed position throughout the endoluminal procedure.

An introducer (not shown), which supports branch stent-graft 138, having an interior surface of loops 142, as shown in Figure 10, is then inserted into the vasculature and over the guidewire where it is maneuvered to the left common iliac artery 104' below the aneurysm. An example of an introducer which may be used in the present invention is that shown in U.S. Patent No. 5,683,450, to Goicoechea et al. A balloon catheter (not shown) is then extended while maintaining the outer sheath of the introducer in a fixed position in order to position the balloon above the renal arteries.

The introducer is then positioned to place branch stent-graft 138 within the left common iliac artery 104'. Proper placement may be facilitated with the use of

radiopaque markers. Once the introducer is properly positioned, the balloon is inflated to occlude the aorta.

The outer sheath of the introducer is then withdrawn until the proximal end of branch stent-graft 138 emerges from the outer sheath. Using a radiopaque marker disposed on the proximal end of the prosthesis, the introducer is maneuvered until precise positioning of branch stent-graft 138 within the left common iliac artery is obtained. Once branch stent-graft 138 has been properly positioned, the outer sheath of the introducer is fully withdrawn, allowing branch stent-graft 138 to radially expand, thereby contacting the endoluminal surface of the left common iliac artery 104'.

Once branch stent-graft 138 has been properly positioned, the balloon is deflated and drawn into the lumen of branch stent-graft 138, where it may be inflated to further secure branch stent-graft 138 to the endoluminal wall of the left common iliac artery 104'. The balloon is then deflated and maintained within the lumen of branch stent-graft 138 where it will be used to secure main stent-graft 132 thereto. Additionally, the introducer may be withdrawn from the vasculature, leaving the guidewire in place.

Main stent-graft 132, having an external structure of hooks, is then deployed to the aneurysm. Main stent-graft 132 includes trunk 134 and a right limb 136. Hooks 140 on the exterior surface of trunk 134 are capable of complementary engagement with loops 142 on the interior surface of branch stent-graft 138. A guidewire (not shown) is inserted into the incised right femoral artery and advanced until its distal end is above the

aneurysm within the vasculature. An introducer (not shown) which includes main stent-graft 132 is then inserted into the vasculature and over the guidewire where it is maneuvered to the right common iliac artery 104 below the aneurysm.

Once in the aorta, the introducer is positioned such that the proximal end of its outer sheath is approximately level with the renal arteries. A balloon catheter (not shown) is then extended while maintaining the outer sheath of the introducer in a fixed position such that the balloon is positioned above the renal arteries. The introducer is then positioned to place trunk 134 in the desired deployment location, which may be facilitated with the use of radiopaque markers. Once the introducer is properly positioned, the balloon is inflated to occlude the aorta.

The outer sheath of the introducer is then withdrawn until the proximal end of first stent-graft 132 emerges from the outer sheath. Using a radiopaque marker disposed on the proximal end and/or distal ends of main stent-graft 132, the introducer is rotated until proper alignment of the main stent-graft 132 and branch stent-graft 138 is obtained, such that hooks 140 of main stent-graft 132 align with loops 142 of branch stent-graft 138 such that there is sufficient overlap between the first and second stent grafts to ensure that a substantially fluid tight seal will form therebetween. Once properly positioned, the outer sheath of the introducer is withdrawn sufficiently as to cause trunk 134 to radially expand and contact the endoluminal surface of the abdominal aorta while also causing hooks 140 to engage loops 142. The outer sheath of the introducer is then further

withdrawn to deploy right limb 136 of main stent-graft 132 within the right common iliac artery 104, such that it radially expands it contacts the endoluminal surface thereof.

The deflated balloon contained within the lumen of branch stent-graft 1382 may then be inflated to provide a force against the inner surface of main stent-graft 132 at the point where hooks 140 present on the exterior surface thereof engage loops 142 on the interior surface of branch stent-graft 138, thereby securing hooks 140 to loops 142, ensuring that a substantially fluid tight seal is created therebetween. Both balloons are then deflated to allow blood to flow through the thus-assembled bifurcated prosthesis 130, shown in Figure 9, such that main stent-graft 132 partially overlays branch stent-graft 138 at the point where hooks 140 and loops 142 engage one another, thereby providing a cuff which promotes the fluid tight characteristic of assembled stent-graft 130.

Alternatively, the above procedure may be performed such that main stent-graft 132 is deployed at the aneurysm prior to deployment of branch stent-graft 138, such that a hook or loop structure on main stent-graft 132 will engage a hook or loop structure on branch stent graft 138, which is positioned partially inside of main stent-graft 132 such that there is an overlap therebetween. Additionally, either main stent-graft 132 or branch stent-graft 138 may have either of hooks 140 or loops 142 thereon, so long as the stent-grafts are mated in a complementary manner when engaged with one another. It will further be appreciated that main stent-graft 132 and branch stent-graft 138 may be shaped to facilitate alignment and mating therebetween, for example, main stent-graft 132 may

be a frustoconical member adapted for engaging branch stent-graft 138, also a frustoconical member.

While the invention has been illustrated and described herein in terms of its use as an endoprosthesis for treating an aneurysm, it will be apparent to those skilled in the art that the prosthesis can be used in other instances in other vessels of the body. Further, while stent-grafts have been described for use in the present invention, grafts and stents alone may also be used in the present invention.

WHAT IS CLAIMED IS:

1. An endovascular prosthesis comprising:

a. an endovascular member having a structure comprising one of a hook structure and a loop structure;

b. a patch for placement against said endovascular member, said patch having a structure comprising the other of said hook structure and said loop structure;

wherein said hook structure and said loop structure are matingly engageable so as to maintain said patch in substantially fluid tight engagement with said endovascular member.

2. The endovascular prosthesis of claim 1, wherein said endovascular member is selected from the group consisting of grafts, stents and stent-grafts.

3. The endovascular prosthesis of claim 1, wherein said hook and loop structures are comprised of textile materials.

4. The endovascular prosthesis of claim 1, wherein said hook and loop structures are selected from the group consisting of polypropylene, polyethylene teraphthalate, polyurethane, a copolyester elastomer, and nylon.

5. A method of repairing a damaged area of an endovascular prosthesis having a hook or loop structure and which is positioned within a body lumen, comprising the step of:

attaching a patch to an endovascular member, wherein said patch has a hook or loop structure cooperative with a hook or loop structure of said endovascular member for maintaining said patch in substantially fluid tight communication with said endovascular member.

6. The method of claim 5, further comprising the step of delivering said patch to said endovascular member through a body lumen containing said endovascular member.

7. The method of claim 5, wherein said patch comprises one of a hook structure and a loop structure and said endovascular member comprises the other of said hook structure and said loop structure.

8. The method of claim 5, wherein said attaching step occurs *in situ*.

9. The method of claim 5, wherein said attaching step is effected by expanding a balloon affixed to a catheter to cause said hook or loop structure of said patch to engage the other of said hook or loop structure of said endovascular member.

10. The method of claim 6, wherein said delivery step is effected by use of a catheter.

11. The method of claim 6, wherein said delivery step is effected by use of a balloon catheter.

12. A multi-component endovascular prosthesis comprising:

a. a first prosthetic component, said first prosthetic component having a structure comprising one of a hook structure and a loop structure;

b. a second prosthetic component, said second endovascular component having a structure comprising the other of said hook structure and said loop structure;

wherein said hook structure and said loop structure are matingly engageable so as to maintain said first prosthetic component in substantially fluid tight engagement with said second prosthetic component.

13. The multi-component endovascular prosthesis of claim 12, wherein said hook and loop structures are comprised of textile materials.

14. The multi-component endovascular prosthesis of claim 12, wherein said hook and loop structures are comprised of a material selected from the group consisting of polypropylene, polyethylene teraphthalate, polyurethane, a copolyester elastomer, and nylon.

15. A bifurcated endovascular prosthesis comprising:

a. a main prosthetic component, said main prosthetic component having a structure comprising one of a hook structure and a loop structure;

b. a branch prosthetic component, said branch endovascular component having a structure comprising the other of said hook structure and said loop structure;

wherein said hook structure and said loop structure are matingly engageable so as to maintain said main prosthetic component in substantially fluid tight engagement with said branch prosthetic component.

16. The bifurcated endovascular prosthesis of claim 15, wherein said hook and loop structures are comprised of textile materials.

17. The bifurcated endovascular prosthesis of claim 15, wherein said hook and loop structures are comprised of a material selected from the group consisting of polypropylene, polyethylene teraphthalate, polyurethane, a copolyester elastomer and nylon.

18. A method for the assembly of an endovascular prosthesis which is implantable within a body lumen, comprising the steps of:

a) providing a first prosthetic component having one of a hook or loop structure;

b) providing a second prosthetic component having the other of said hook or loop structure;

c) engaging said hook structure or said loop structure of said first prosthetic component with the other of said hook structure or said loop structure of said second prosthetic component so as to maintain said first prosthetic component in substantially fluid tight engagement with said second prosthetic component.

19. The method of claim 18, wherein said engaging step occurs *in situ*.

20. The method of claim 18, wherein said engaging step is effected by expanding a balloon affixed to a catheter to cause said hook or loop structure of said first prosthetic component to engage the other of said hook or loop structure of said second prosthetic component.

21. The method of claim 18, wherein said endovascular prosthesis is useful for the treatment of aneurysms.

22. The method of claim 21, wherein said aneurysms are abdominal aortic aneurysms.

23. A method for the assembly of a bifurcated endovascular prosthesis which is implantable within a body lumen, comprising the step of:

a) providing a main prosthetic component having one of a hook or loop structure;

b) providing a branch prosthetic component having the other of said hook or loop structure;

c) engaging said hook structure or said loop structure of said main prosthetic component with the other of said hook structure or said loop structure of said branch prosthetic component so as to maintain said main prosthetic component in substantially fluid tight engagement with said branch prosthetic component.

24. The method of claim 23, wherein said engaging step occurs *in situ*.

25. The method of claim 23, wherein said engaging step is effected by expanding a balloon affixed to a catheter to cause said hook or loop structure of said main prosthetic component to engage the other of said hook or loop structure of said branch prosthetic component.

26. The method of claim 23, wherein said bifurcated endovascular prosthetic device is useful for the treatment of aneurysms.

27. The method of claim 26, wherein said aneurysms are abdominal aortic aneurysms.

ENDOVASCULAR PROSTHETIC DEVICES HAVING HOOK AND LOOP STRUCTURES

ABSTRACT OF THE DISCLOSURE

Endovascular prostheses and methods for their use are disclosed. The prostheses include an endovascular member in need of repair and a patch therefore, as well as prostheses comprising two or more endovascular members, such as stent-grafts, which may be assembled *in situ*. Components of the prostheses are held together in substantially fluid tight engagement as the result of hook and loop structures which are present on the members. The hooks engage the loops to secure the components to one another. As a result, the present invention is particularly useful for the *in situ* repair of damaged prostheses and for the *in situ* assembly of bifurcated endovascular prostheses, particularly for the treatment of abdominal aortic aneurysms.

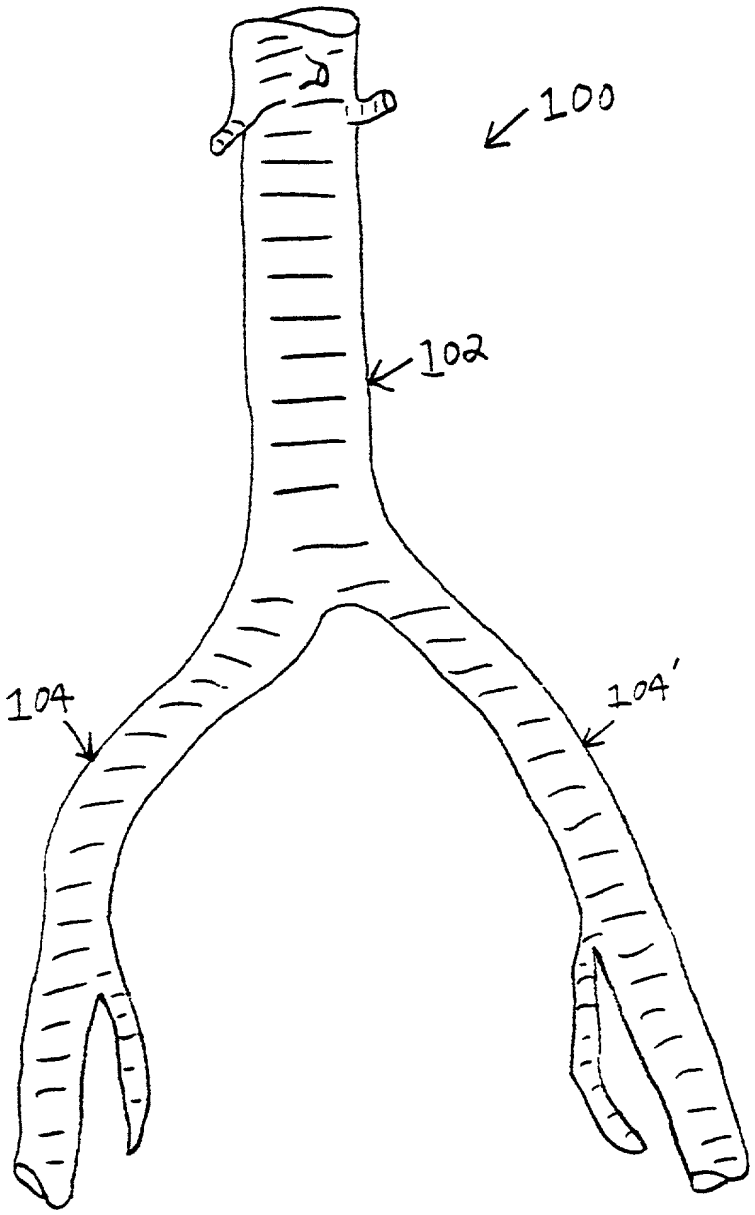

FIG. 1

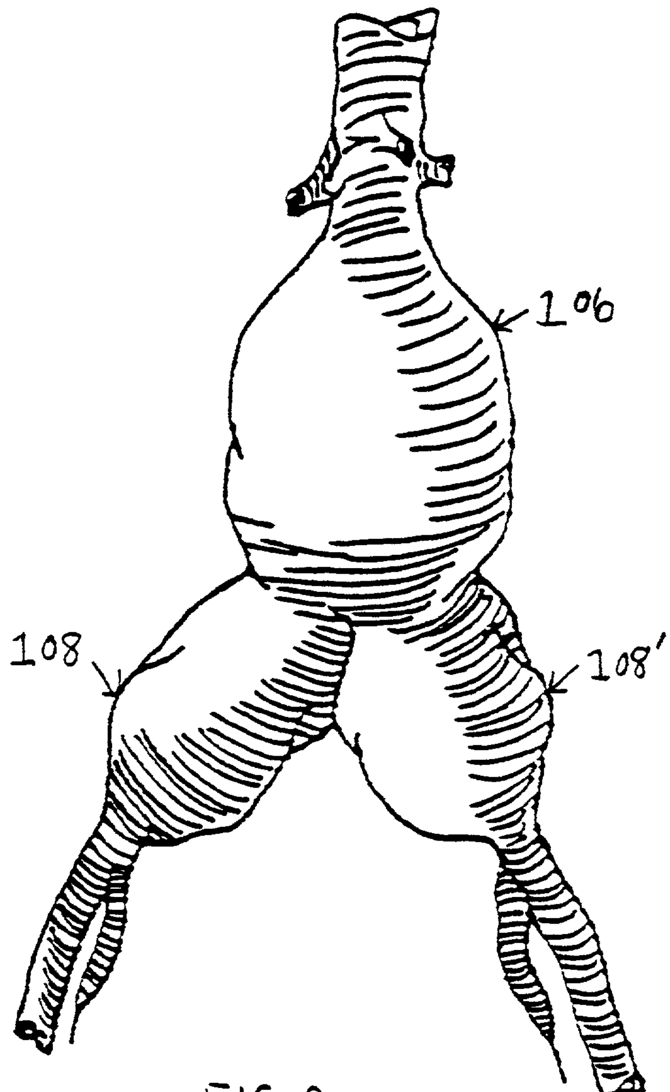

FIG. 2

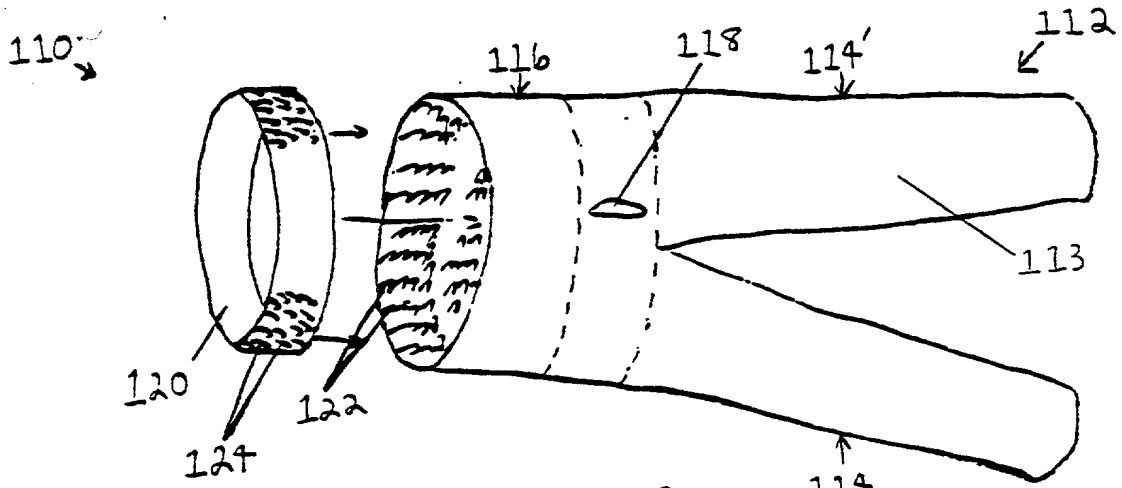

FIG. 3

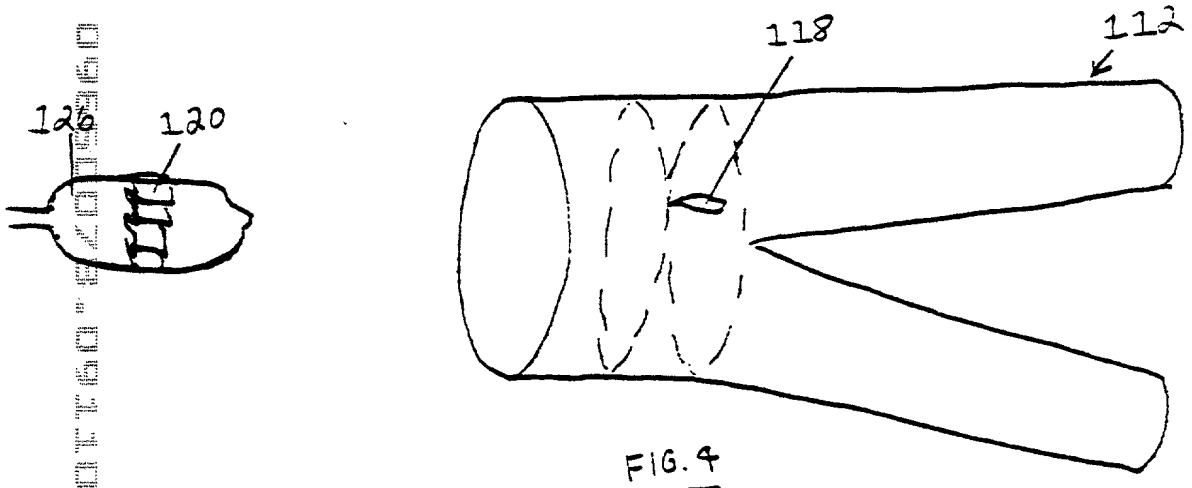

FIG. 4

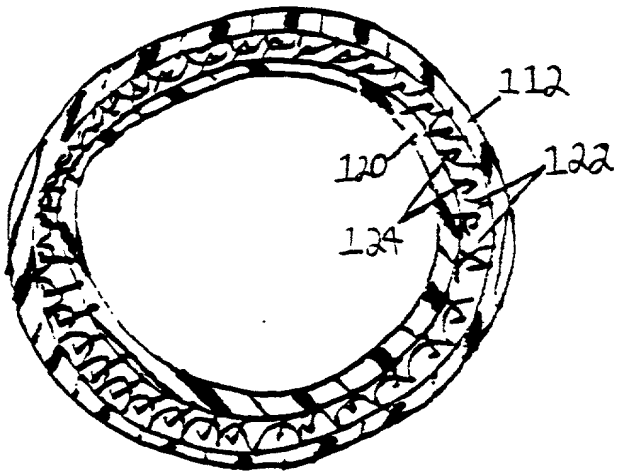

FIG. 5

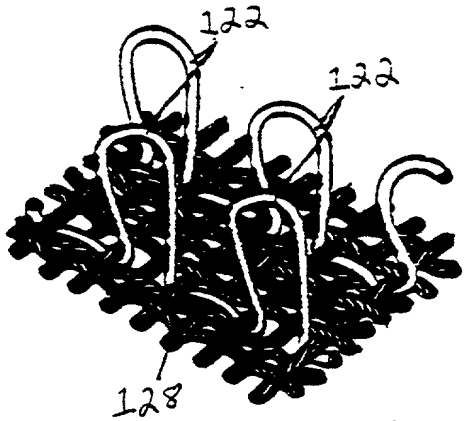

FIG. 6

FIG. 7

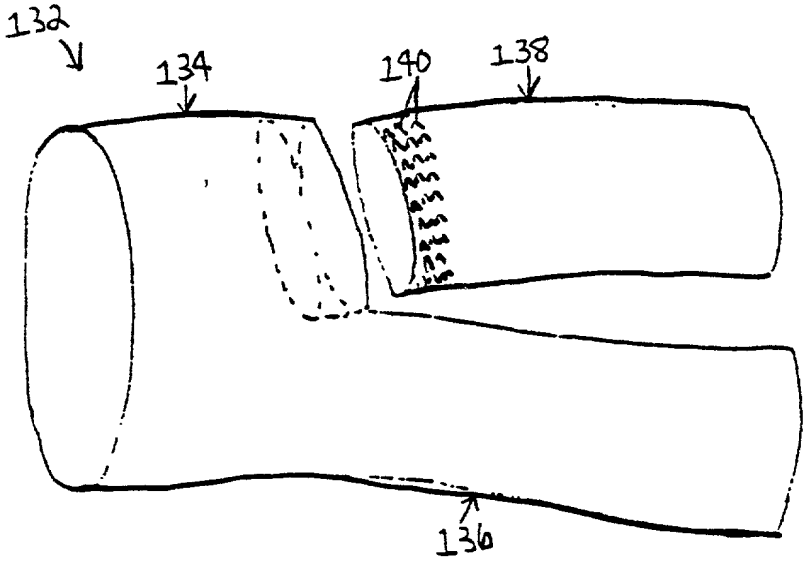

FIG. 8

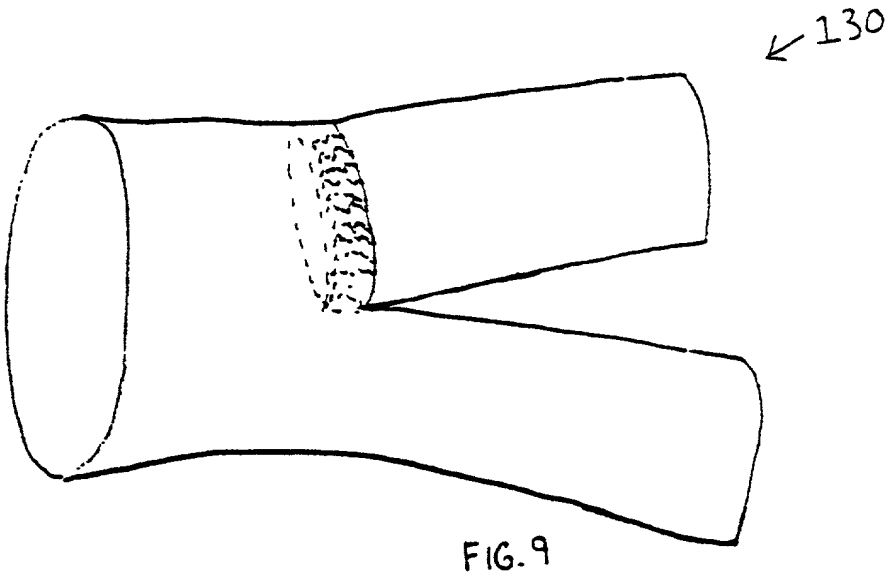

FIG. 9

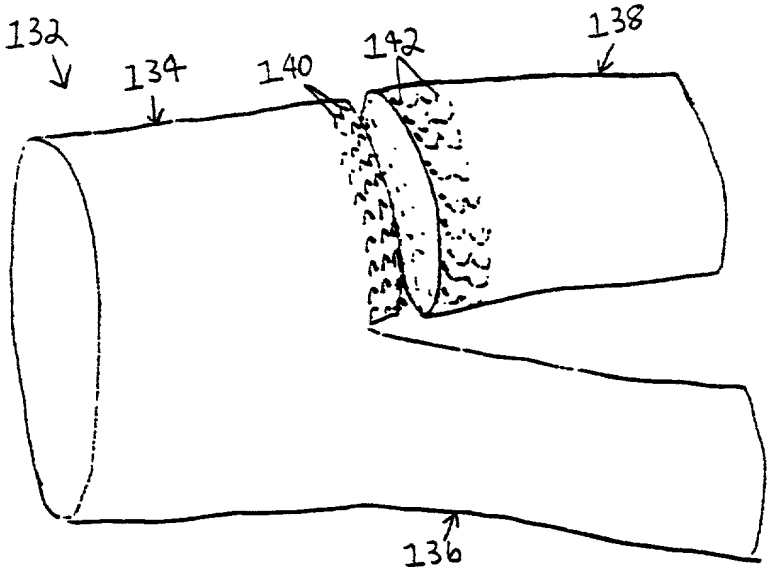

FIG. 10

PATENT

Attorney's Docket No. **498-239**

COMBINED DECLARATION AND POWER OF ATTORNEY

(ORIGINAL, DESIGN, NATIONAL STAGE OF PCT, SUPPLEMENTAL, DIVISIONAL, CONTINUATION OR CIP)

As a below named inventor, I hereby declare that:

TYPE OF DECLARATION

This declaration is of the following type: *(check one)*

- ☒ Original
- ☐ Supplemental
- ☐ Design
- ☐ National Stage PCT
- ☐ Divisional
- ☐ Continuation
- ☐ Continuation-in-Part (CIP)

INVENTORSHIP IDENTIFICATION

NOTE: If the inventors are each not the inventors of all the claims an explanation of the facts, including the ownership of all the claims at the time the last claimed invention was made, should be submitted.

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

ENDOVASCULAR PROSTHETIC DEVICES HAVING HOOK AND LOOP STRUCTURES

the specification of which: *(complete (a), (b) or (c))*

(a) ☒ is attached hereto.

(b) ☐ was filed on _____ as
☐ Serial No. **08/**_____ or
☐ Express Mail No. _____, as Serial No. not yet known and was amended on _____. *(If applicable)*

(c) ☐ was described and claimed in PCT International Application No. **PCT/** _____ filed on _____ and as amended under PCT Article 19 on _____. *(If any)*

ACKNOWLEDGMENT OF REVIEW OF PAPERS AND DUTY OF CANDOR

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above, and that the filing of said specification, if heretofore filed, was authorized by me.

I acknowledge the duty to disclose information which is material to the patentability of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a).

CLAIM OF PRIORITY OF EARLIER FOREIGN APPLICATION(S) UNDER 35 U.S.C. §119(a)-(d)

I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor's certificate or of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed:

(List prior foreign/PCT application(s) filed within 12 months (6 months for design) prior to this U.S. application.)

NOTE: Where item (c) is entered above and the International Application which designated the U.S. claimed priority check item (e), enter the details below and make the priority claim.

COUNTRY (orPCT)	APPLICATION NO.	DATE OF FILING *(Day/Month/Year)*	PRIORITY CLAIMED UNDER 35 USC §119
			☐ YES ☐ NO
			☐ YES ☐ NO

CLAIM FOR BENEFIT OF PRIOR U.S. PROVISIONAL APPLICATION(S) UNDER 35 U.S.C. §119(e)

I hereby claim the benefit under Title 35, United States Code, §119(e) of any United States provisional application(s) listed below:

(List prior U.S. provisional applications.)

PROVISIONAL APPLICATION NO.	FILING DATE *(Day/Month/Year)*

CLAIM FOR BENEFIT OF EARLIER U.S./PCT APPLICATION(S) UNDER 35 U.S.C. 120

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) or PCT international application(s) designating the United States of America that is/are listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in such prior application(s) in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application(s) and the national or PCT international filing date of this application:

(List prior U.S. applications or PCT international applications designating the U.S. for benefit under 35 U.S.C. §120.)

U.S. APPLICATIONS		STATUS *(Check One)*		
U.S. SERIAL NO.	U.S. FILING DATE *(Day/Month/Year)*	Patented	Pending	Abandoned
0 /		☐	☐	☐
0 /		☐	☐	☐

PCT APPLICATIONS DESIGNATING THE U.S.			STATUS *(Check One)*		
PCT APPLN. NO.	PCT FILING DATE *(Day/Month/Year)*	U.S. SERIAL NOS ASSIGNED (If any)	Patented	Pending	Abandoned
PCT/			☐	☐	☐
PCT/			☐	☐	☐

35 USC 119 PRIORITY CLAIM, IF ANY, FOR ABOVE LISTED U.S./PCT APPLICATIONS

PRIORITY APPLICATION NO.	PRIORITY COUNTRY	FILING DATE *(Day/Month/Year)*	ISSUE DATE *(Day/Month/Year)*

POWER OF ATTORNEY

As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office in connection therewith:

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PLEASE SEND CORRESPONDENCE TO:	PLEASE DIRECT TELEPHONE CALLS TO:
Daniel A. Scola, Jr. HOFFMANN & BARON, LLP 6900 Jericho Turnpike Syosset, NY 11791	Keith R. Lange (973) 331-1700

DECLARATION

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

SIGNATURE(S)

Full Name of Sole or First Inventor:	John K. Smith
Country of Citizenship:	USA
Residence Address:	44 Sawyer Avenue, Medford, MA 02155
Post Office Address:	**Same as above**
Date: 8/28/00	Inventor's signature J. K. Smith

NOTE: All above spaces identifying inventors must be completed or deleted before any inventor executes this application